

REMARKS

This reply is fully responsive to the Office Action dated April 3, 2008, and is filed within six - (6) months following the mailing date of the Office Action. The Commissioner is authorized to treat this response as including a petition to extend the time period pursuant to 37 CFR 1.136(a) requesting an extension of time of the number of months necessary to make this response timely filed. The method of payment and fees for petition fee due in connection therewith is enclosed.

Objection/Rejection Summary

This application has been carefully reviewed in light of the Office Action of April 3 , 2008, wherein:

- A. Claims 1, 3, 4, 7-20, 22, 23, 26-39, 41, 42, 45-59, 61-67, 69-75, and 77-81 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter;
- B. Claims 1, 3, 4, 9-17, 58, 59, 62-65 were rejected under 35 U.S.C. 102(b) as being anticipated by Caron et al. (hereinafter referred to as the Caron publication); and
- C. Claims 1, 18-20, 22, 23, 28-39, 41, 42, 47-57, 66, 67, 70-75, and 78-81 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Caron publication in view of Kanehisa et al. (hereinafter referred to as the Kanehisa publication).

Claim Rejections – 35 U.S.C. §101

- A. Turning now to the Office Action, Claims 1, 3, 4, 7-20, 22, 23, 26-39, 41, 45-59, 61-67, 69-75, and 77-81 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The Examiner rejected Claims 1, 3, 4, 7-20, 22, 23, 26-39, 41, 45-59, 61-67, 69-75, and 77-81 under 35 U.S.C. 101 as being directed to non-statutory subject matter and concluded that the claims do not require production of a tangible result in a form that is useful to the user of the process or apparatus. The Examiner further stated that the rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, or in a graphical format, or in a user

readable format, or by including a result that is a physical transformation. The Applicant respectfully directs the Examiner to independent Claims 1, 20, 39, 58, 66, and 74 which have been amended to include the limitation of “...providing an output to a user.” No new subject matter has been introduced as the present application states, “Output to a user is preferably provided on a video display such as a computer screen, but may also be provided via printers or other means. Output may also be provided to other devices or other programs for use therein” (paragraph [59]). Additionally, FIG. 3 of the present application illustrates a block diagram depicting the components of a computer system used in the present invention, including an output to a display.

Additionally, the Examiner stated that Claims 20, 22, 23, 26-39, 41, 42, 45-57, 66, 67, 69-75, and 77-81 are drawn to a computer program on computer readable media. The Examiner added that a review of the specification does not show a definition of computer readable media such that excludes an embodiment that is information on a carrier wave. The Examiner further concluded that as such, an embodiment of the claims read on non-statutory subject matter. The Applicant respectfully directs the Examiner to the present application which states, “The computer program product generally represents computer readable code stored on a computer readable medium such as an optical storage device, e.g., a compact disc (CD) or digital versatile disc (DVD), or a magnetic storage device such as a floppy disk or magnetic tape. Other, non-limiting examples of computer readable media include hard disks and flash-type memories” (paragraph [58]).

While the specification does not specifically exclude information on a carrier wave, a carrier wave is defined as “a waveform that is modulated with an input signal for the purpose of conveying information...” (http://en.wikipedia.org/wiki/Carrier_wave). Furthermore, claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage or the strength of a magnetic field, define energy or magnetism, *per se*, and as such are nonstatutory natural phenomena. *O’Reilly v. Morse*, 56 U.S. (15 How. 62, 112-14 (1853)). However, a signal claim directed to a practical application of electromagnetic energy is statutory regardless of its transitory nature. See

O'Reilly, 56 U.S. at 114-19; *In re Breslow*, 616 F.2d 516, 519-21, 205 USPQ 221, 225-26 (CCPA 1980). Clearly, a carrier wave which modulates an input signal for the purpose of conveying information could be considered statutory subject matter given the aforementioned definition and guidelines. Regardless of whether a carrier wave could be considered statutory subject matter, the Applicant respectfully submits that a carrier wave is not a claimed limitation in the present application.

Nevertheless, the present application now includes a limitation of "providing an output to a user," which is clearly a physical transformation and, therefore, statutory subject matter.

Thus, the Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1, 3, 4, 7-20, 22, 23, 26-39, 41, 45-59, 61-67, 69-75, and 77-81 under 35 U.S.C. §101 and provide for timely allowance of all pending claims.

Claim Rejections – 35 U.S.C. §102

- B. Claims 1, 3, 4, 9-17, 58, 59, 62-65 were rejected under 35 U.S.C. 102(b) as being anticipated by the Caron publication.

Claims 1 and 58

The Examiner rejected Claims 1 and 58 as being anticipated by the Caron publication. In order to establish a prima facie case of anticipation, the Examiner must set forth an argument that provides (1) a single reference (2) that teaches or enables (3) each of the claimed elements (as arranged in the claim) (4) either expressly or inherently and (5) as interpreted by one of ordinary skill in the art. All of these factors must be present, or a case of anticipation is not met. Thus, "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

The Applicant respectfully asserts that the cited prior art fails to teach each element of the claimed invention. The Applicant respectfully directs the Examiner to the currently

amended Claims 1 and 58 which include the limitation “...determining a start and a stop position for each exon...”

The present invention is to be contrasted with the Caron publication. The Examiner stated that the Caron publication details results from a complete human transcriptome map using SAGE expression data which is derived from processed cDNA transcripts, known in the art to consist of exons. The Examiner further stated that the Caron publication shows an expression map of human chromosome 11 and notes the presence of regions of increased gene expression.

The Applicant respectfully asserts that cDNA is complementary DNA synthesized from a mature mRNA template. Introns are spliced out of a primary RNA transcript before it becomes mRNA. Thus, cDNA only codes for exons and any data derived from cDNA would not take into account the spatial arrangement of exons and introns. The present invention discloses integration of expression data with a spatial distribution of the gene's intron/exon structure information. Therefore, to distinguish the present invention from the cited prior art, Claims 1 and 58 have been amended to clarify that forming a spatial-expression pattern according to the present invention includes the step of “determining a start and a stop position for each exon.” Support for this amendment can be found in paragraph [65] of the present application which states, “For every gene the start and stop position of the gene and its constituent exons is determined.”

Additionally, it should also be noted that nowhere in the cited prior art can be found any reference to the limitation found in Claims 1 and 58 which disclose “...a magnitude of the first spatial-expression pattern signal at any point is determined by an expression level of the corresponding exon.” The present invention is to be contrasted with the Caron publication, where the mapping is performed at the gene level, NOT the exon level. At its finest resolution, the Caron publication maps “expression levels...for...individual tags of a gene” (Caron publication, pg. 1290, col. 3, first paragraph). Additionally, FIG. 2 of the Caron publication illustrates the mapping is to a marker comprising a 10 base pair region, not a corresponding exon. Thus, at its finest

resolution, the Caron publication discloses mapping of expression levels to only a 10 base pair region. Although the marker may overlap an exon, the mapping is NOT associated with a corresponding exon having a determined start and stop position as disclosed in Claims 1 and 58 of the present application.

Thus, the Caron publication is clearly distinguishable from the invention claimed in Claims 1 and 58 of the present application. Therefore, the Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1 and 58 under 35 U.S.C. §102 and provide for timely allowance of all pending claims.

Claims 3, 4, 9-17, 59, and 62-65

Regarding Claims 3, 4, 9-17, 59, and 62-65, the Applicant directs the Examiner to the comments above regarding Claims 1 and 58. Since Claims 3, 4, 9-17, 59, and 62-65 depend from Claims 1 and 58, respectively, they incorporate all of the limitations of their respective independent Claims 1 and 58 and, therefore, Claims 3, 4, 9-17, 59, and 62-65 are patentable for at least the same reasons given with respect to their respective independent Claims 1 and 58. Thus, the Applicant respectfully requests that the Examiner withdraw this rejection of Claims 3, 4, 9-17, 59, and 62-65 under 35 U.S.C. §102.

Claim Rejections – 35 U.S.C. §103

- C. Claims 1, 18-20, 22, 23, 28-39, 41, 42, 47-57, 66, 67, 70-75, and 78-81 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Caron publication in view of the Kanehisa publication.

Claims 1, 20, 39, 66, and 74

The Examiner rejected Claims 1, 20, 39, 66, and 74 as being unpatentable over the Caron publication in view of the Kanehisa publication. Establishing a *prima facie* case of obviousness requires: (A) determining the scope and contents of the prior art; (B) ascertaining the differences between the prior art and the claims in issue; (C) resolving

the level of ordinary skill in the pertinent art; and (D) evaluating evidence of secondary considerations. *See Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). Proper analysis of obviousness is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. 35 U.S.C. 103(a).

Recently, the Supreme Court stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *See KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) *quoting In re Kahn*, 441 F. 3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

The rationale to support a conclusion that the claim would have been obvious is that “a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F. 3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006).

Additionally, in order to establish a *prima facie* case of obviousness of a claimed invention, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

The Applicant respectfully asserts that the cited prior art fails to teach each element of the claimed invention. The Applicant respectfully directs the Examiner to the currently amended Claims 1, 20, 39, 66, and 74 which include the limitation “...determining a start and a stop position for each exon...”

The present invention is to be contrasted with the Caron publication. The Examiner stated that the Caron publication details results from a complete human transcriptome map using SAGE expression data which is derived from processed cDNA transcripts, known in the art to consist of exons. The Examiner further stated that the Caron publication shows an expression map of human chromosome 11 and notes the presence of regions of increased gene expression.

The Applicant respectfully asserts that cDNA is complementary DNA synthesized from a mature mRNA template. Introns are spliced out of a primary RNA transcript before it becomes mRNA. Thus, cDNA only codes for exons and any data derived from cDNA would not take into account the spatial arrangement of exons and introns. The present invention discloses integration of expression data with a spatial distribution of the gene's intron/exon structure information. Therefore, to distinguish the present invention from the cited prior art, Claims 1, 20, 39, 66, and 74 have been amended to clarify that forming a spatial-expression pattern according to the present invention includes the step of "determining a start and a stop position for each exon." Support for this amendment can be found in paragraph [65] of the present application which states, "For every gene the start and stop position of the gene and its constituent exons is determined."

Additionally, it should also be noted that nowhere in the cited prior art can be found any reference to the limitation found in Claims 1, 20, 39, 66, and 74 which disclose "...a magnitude of the first spatial-expression pattern signal at any point is determined by an expression level of the corresponding exon." The present invention is to be contrasted with the Caron publication, where the mapping is performed at the gene level, NOT the exon level. At its finest resolution, the Caron publication maps "expression levels...for...individual tags of a gene" (Caron publication, pg. 1290, col. 3, first paragraph). Additionally, FIG. 2 of the Caron publication illustrates the mapping is to a marker comprising a 10 base pair region, not a corresponding exon. Thus, at its finest resolution, the Caron publication discloses mapping of expression levels to only a 10 base pair region. Although the marker may overlap an exon, the mapping is NOT associated with a corresponding exon having a determined start and stop position as disclosed in Claims 1, 20, 39, 66, and 74 of the present application.

Thus, neither the Caron publication nor the Kanehisa publication, either alone or combined, teaches each of the claimed elements of Claims 1, 20, 39, 66, and 74. Therefore, the Applicant respectfully requests that the Examiner withdraw this rejection under 35 U.S.C. §103 and provide for timely allowance of all pending claims.

Claims 18, 19, 22, 23, 28-38, 41, 42, 47-57, 67, 70-73, 75, and 78-81

Regarding Claims 18, 19, 22, 23, 28-38, 41, 42, 47-57, 67, 70-73, 75, and 78-81, the Applicant directs the Examiner to the comments above regarding Claims 1, 20, 39, 66, and 74. Since Claims 18, 19, 22, 23, 28-38, 41, 42, 47-57, 67, 70-73, 75, and 78-81 depend from Claims 1, 20, 39, 66, and 74, respectively, they incorporate all of the limitations of their respective independent Claims 1, 20, 39, 66, and 74 and, therefore, Claims 18, 19, 22, 23, 28-38, 41, 42, 47-57, 67, 70-73, 75, and 78-81 are patentable for at least the same reasons given with respect to their respective independent Claims 1, 20, 39, 66, and 74. Thus, the Applicant respectfully requests that the Examiner withdraw this rejection of Claims 18, 19, 22, 23, 28-38, 41, 42, 47-57, 67, 70-73, 75, and 78-81 under 35 U.S.C. §103 and provide for timely allowance of all pending claims.

CONCLUSION

The Applicant respectfully submits that in light of the above amendment/remarks, all claims are now in allowable condition. The Applicant thus respectfully requests timely allowance of all of the pending claims.

Any claim amendments that are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those skilled in the art to clearly understand the scope of the claim language. Furthermore, any new claims presented above are of course intended to avoid the prior art, but are not intended as replacements or substitutes of any cancelled claims. They are simply additional specific statements of inventive concepts described in the application as originally filed.

Further, it should be noted that amendment(s) to any claim is intended to comply with the requirements of the Office Action in order to elicit an early allowance, and is not intended to prejudice Applicant's rights or in any way to create an estoppel preventing Applicant from arguing allowability of the originally filed claim in further off-spring applications.

In the event the Examiner wishes to discuss any aspect of this response, or believes that a conversation with either Applicant's or Applicants' representative would be beneficial, the Examiner is encouraged to contact the undersigned at the telephone number indicated below.

The Commissioner is authorized to charge any additional fees that may be required or credit overpayment to the attached credit card form. In particular, if this response is not timely filed, the Commissioner is authorized to treat this response as including a petition to extend the time period pursuant to 37 CFR 1.136(a) requesting an extension of time of the number of months necessary to make this response timely filed. The petition fee due

in connection therewith may be charged to deposit account no. 50-2738 if a credit card form has not been included with this correspondence, or if the credit card could not be charged.

Respectfully submitted,

A handwritten signature in black ink, consisting of a large, stylized 'C' followed by a long, sweeping horizontal line that ends in a small upward hook.

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